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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,528	09/10/2003	Cary James Miller	215105.01400	1959
27160 7590 09/25/2008 KATTEN MUCHIN ROSENMAN LLP (C/O PATENT ADMINISTRATOR) 2900 K STREET NW, SUITE 200 WASHINGTON, DC 20007-5118				
EXAMINER				
ALEXANDER, LYLE				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
09/25/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/658,528

Applicant(s)

MILLER ET AL.

Examiner

Lyle A. Alexander

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/309)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Krieger on 9/23/08.

In the last line of claim 5 after "location" –, wherein the device is configured to expel a metered portion of the sample through the capillary stop – has been added.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6,8-10,13-14 and 16-24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zelin (USP 5,821,399).

Zelin teach a method and apparatus for the testing of biological fluids. Figures 2-5 teach a device comprising a housing comprising at least one planar surface, a fluid addition orifice in fluid communication with an internal holding chamber, a capillary that stops the added fluid from entering the analysis chamber until it is actuated which has been read on the claimed "expelling a metered portion of the sample through the capillary stop." The insertion of the device(10) into the reader(150) performs the

claimed function of "... displaces any excess fluid sample away from the orifice, seals the fluid sample within the holding chamber ...".

Claims 1-24 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Davis et al. (USP 7,419,821).

Davis et al. is available as prior art because the inventive entity is different even though there is one invention in common. Davis et al. teach the same structure as presently claimed. The method is best summarized in column 20-21 lines 58-3 respectively which is indistinguishable from that presently claimed.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 7,11-12 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zelin.

See Zelin *supra*.

Zelin is silent to the claimed plastic and the claimed volumes.

The court decided In re Boesch (205 USPQ215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The selection of a particular plastic or the volume of analysis are both result effective variable that have well known and expected results. Plastics are well known for being inert, inexpensive, lightweight and durable. The selection of the analysis volume is based upon the sample easily obtainable and the minimization of reagent to minimize the cost of each test.

It would have been within the skill of the art to modify Zelin and use a polyester, ABS or acetal plastic as optimization of a result effective variable and to gain the above advantages. It would have been within the skill of the art to further modify Zelin and use the claimed volumes of 5-50 microliters as well as the claimed orifice in the range of 1-2 mm as optimization of a result effective variable and to gain the above advantages.

Response to Arguments

Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander
Primary Examiner
Art Unit 1797

/Lyle A Alexander/
Primary Examiner, Art Unit 1797